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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/622,629 | 10/20/2000 | David A. Mark | 112701-006 | 8726 |

29157 7590 11/20/2002

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EXAMINER

SHARAREH, SHAHNAM J

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1617

DATE MAILED: 11/20/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/622,629

Applicant(s)

MARK ET AL.

Examiner

Shahnam Sharareh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 August 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Amendment filed on August 02, 2002 has been entered. Claims 1, 3-15 are pending in this application. Any rejection that is not addressed in this Office Action is considered obviated in view of the Amendment.

Double Patenting

2. Claims 1-15 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of copending Application No. 09/759,037. Applicant's intention to file a Terminal Disclaimer is noted when pending claims are allowed.

Response to Arguments

3. With respect to the pending rejections, Applicant's arguments filed August 02, 2002 have been fully considered but they are not persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 102

4. Claims 1, 3-7, 9-15 stand rejected under 35 U.S.C. 102(b) as being anticipated by Schmidl et al US Patent 5,504,072.

Applicant argues that Schmidl does not teach the instant energy density of about 1.4 to about 1.8 kcal/ml.

In response, Examiner states that under the principles of inherency, a prior art that does not expressly disclose claim limitations anticipates the claims, if it necessarily functions in accordance with, or includes, those limitations. *Atlas Powder Co. v. IRECO Inc.* 190 F.3d 1342, 1349 (Fed. Cir. 1999). Inherency is not necessarily coterminous with

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knowledge of those of ordinary skill in art, since artisans of ordinary skill may not recognize inherent characteristics or functioning of prior art, but discovery of previously unappreciated property of prior art composition or of scientific explanation for prior art's functioning, does not render old compositions patentably new to discoverer. *Id.*

Accordingly, a prior art reference may anticipate when the claim limitation or limitations not expressly found in that reference are nonetheless inherent in it. *Verdegaal Bros., Inc. v. Union Oil Co. of Cal.*, 814 F.2d 628, 630 (Fed. Cir. 1987).

In the instant case, all elemental limitations of the instant claims are disclosed by Schmidl, accordingly, Schmidl meets the caloric density of instant claims. Schmidl discloses an enteral formulation comprising a protein source that can provide approximately 16-25% of the calorie distribution of the composition that can include protein hydrolysate such as whey hydrolysate, and partially hydrolyzed protein (see col 4 lines 51-67; col 11, lines 31-37), a carbohydrate source, a lipid source including medium and long chain triglycerides, a Zinc source, a Selenium source, a Taurine source, a Cysteine source, a L-Carnitine source, a Vitamin C source (see col 4 lines 1-51 and col 8 table), anticipating the elemental limitations of the instant claims.

Schmidl's formulation provides a non-protein calorie to grams of nitrogen ratio of ranging from 150:1 to 80:1 (see col 5 lines 64-68 and col 6 lines 1-11) which falls within the instant NPG/N ratio of 90:1. Schmidl's formulations are available in solid powder form to provide such osmolality that falls within 630-690 mOsm, substantially similar to those of the instant product. (see Schmidl, col 7, lines 50-57; see instant specification, p. 7, lines 29-31). Thus, absence the showing of contrary, since Schmidl's compositions

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comprise all elemental components of the instant claims, provides similar range of NPG/N ratio and has substantially the same osmolality as those of the instantly claimed formulations, it inherently contains the same caloric density as the instant formulations. Therefore, Schmidl is anticipatory to the instant claims.

5. Claims 1,10-15 stand rejected under 35 U.S.C. 102(b) as being anticipated by Henningfield et al US Patent 5,221,668

Applicant argues that Hennigfield does not teach the instant partially hydrolysed whey proteins. In response, Examiner states that the instant generic claims are not directed to such limitations, thus, Applicant's arguments are not commensurate with the scope of the pending claims.

Furthermore, Henningfield explicitly claims liquid nutritional products comprising a protein system comprises partially hydrolyzed protein in amounts of 18-24% of the calories, lipids in amounts of 20-30% of the calories, and carbohydrates in amounts of 50-58% of the calories (see abstract table 1, col 6 lines 25-40, col 9 lines 1-68, claims 1, 4, 19 and 22). Henningfield's composition also has a caloric density of about 1.2 to 1.5 Kcal/ml, and a calorie nitrogen ratio of about 112:1 to 145:1. The product of Henningfield et al also provide sufficient amount of vitamins in 1,500 Kcal (see col 13 lines 40-46, claims 21-22.) Thus, Henningfield meet the limitations set forth in the instant claims.

New Grounds of Rejection

6. Claims 1, 3-15 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Gray et al US Patent 5,714,472 in view of Schmidl US Patent 5,504,072.

The teachings of Gray and Schmidl have been described in previous Office Action. Gray's formulation only differs in its final concentration of protein. However, Schmidl reasons for the use of lower amounts of hydrolyzed protein in critically ill patients. In fact, Schmidl sets forth that it is well known in the art that the nitrogen content of the composition can be measured to best fit the needs of critically ill patients; as indicated by Schmidl et al (see col 6 lines 2-9).

It is well-established that merely selecting proportions and ranges is not patentable absent a showing of criticality. In re Becket, 33 USPQ. 33 (C.C.P.A. 1937). In re Russell, 439 F.2nd 1228, 169 U.S.P.Q. 426 (C.C.P.A. 1971). Accordingly, absence the showing of criticality, it would have been *prima facie* obvious to optimize the protein concentration of Gray's compositions by routine experimentation, and employ lower amounts of about 16-18% of such proteins, as suggested by Schmidl, because the ordinary artisan would have had a reasonable expectation of success in achieving the desirable clinical outcome by modifying the caloric density and nitrogen supply of Gray's compositions.

Conclusion

7. No claims are allowed. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action, because the scope of the claims have been modified. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

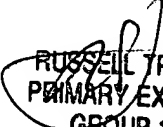
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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 703-308-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.


RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200

SS

November 10, 2002